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14. ABSTRACT
Clinical trials are the primary vehicle for transforming laboratory discoveries in breast cancer care into clinical practice. Enhanced participation by minorities in these trials is necessary to assess the effectiveness of advances in breast cancer care among major subpopulations and to ensure equity in the distribution of research benefits. However, minority participation in clinical trials will likely remain low without research designed to understand the reasons for limited participation. To address persistent ethnic and socioeconomic disparities in cancer care, including participation in research, interventions need to assess the broader context of clinical trials, and include the larger community where these trials take place. Our study examines the combined effect of these factors on minority referral. We have identified trial characteristics that may impact minority recruitment, such as accessibility of trials, linguistic capacity and cultural competence of clinical trial staff, and outreach efforts. We have started to geographic, social and physical attributes of the communities surrounding the trials. Having received approval from the UCSF Committee on Human Research (effective 21 December 2006), we will initiate interviews with research team members and primary care providers to identify key indicators associated with clinical trial referral. This research will provide the basis for a standardized methodology to assess the overall capability of trial sites to include minorities, and contribute to the development of interventions aimed at clinical trial sites and that address specific barriers associated with the social or physical environment.

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Inclusion of Minority Patients in Breast Cancer Clinical Trials: The Role of the Clinical Trial Environment

Celia P. Kaplan, DrPH, MA, Principal Investigator

Annual Report 2007

Introduction

Clinical trials are the primary vehicle for transforming laboratory discoveries in breast cancer care into clinical practice. Enhanced participation by minorities in these trials is necessary to assess the effectiveness of advances in breast cancer care among major subpopulations and to ensure equity in the distribution of new treatment benefits. While inroads to increasing minority inclusion in breast cancer clinical trials have been made,[1-4] recent reports continue to demonstrate lower enrollment among African Americans, Asian Americans, and Latinos when compared to Whites.[5] Within the last decade, the average rate of increase in breast cancer incidence among Latinos and Asian Americans has risen,[6] underscoring the need for minority inclusion in cancer clinical trials. Efforts to recruit minorities into breast cancer clinical trials have not been successful, as evidenced by their significantly lower participation rates compared to Whites.[5] Minority participation will likely remain low without research designed to understand the reasons for limited participation and subsequent policy changes based on those findings. Therefore, to address persistent ethnic and socioeconomic disparities in cancer care, including participation in research, interventions need to assess the broader context or culture of clinical trials, and include the larger community where these trials take place. Our study aims to examine the combined effect of these factors on minority referral. To achieve this, we will measure NIH and pharmaceutical trial characteristics that may impact minority recruitment, such as accessibility and availability of trials, patient burden and benefit, site cultural competence, and outreach efforts. We will also examine the social and physical characteristics of the community surrounding the trials. We will identify key indicators associated with clinical trial referral, in order to establish the basis for a standardized methodology to assess the overall capability of clinical trial sites to include minorities. The proposed study will extend our current state of knowledge about factors affecting referral and participation of minorities into clinical trials. Results will contribute to the development of interventions aimed at clinical trial sites and that address specific barriers associated with the social or physical environment.

Body

Task 1. Identify Breast Cancer Clinical Trials (Months 1-6): We have identified all active breast cancer trials currently being conducted in California, Florida, Illinois and New York listed on Physicians Data Query (PDQ®), the National Cancer Institute's comprehensive clinical trial cancer database (http://www.cancer.gov/cancertopics/pdq/cancerdatabase). To be included in the study, clinical trials must be a) breast cancer treatment trial; and b) open to participation between 1 July 2006 and 30 June 2007. We have developed procedures to download new clinical trials from the NCI website each month. As of 27 March 2007, we have entered 197 clinical trials and 401 clinical trial sites to the database. Information for each trial was retrieved and printed, and each trial was assigned a unique identifier. We identified key characteristics of the trials, and established a database using Microsoft Access. Turning our attention to clinical trial sites, we again reviewed each trial to identify the sites at which the trials take place, and assigned a unique identifier to each site. We searched for site addresses on the internet; when information was unavailable or incomplete, we phoned sites to confirm the address. For sites that have multiple addresses, we captured all the addresses, and confirmed by phone or internet search the specific address where the trial is taking place. In addition to these tables, our database contains queries for running frequencies and merging data in other applications (such as MS Word), and forms for data entry and record retrieval. Site address data was exported to ArcView 9.2, a map-making application, for geocoding. We then generated preliminary maps of clinical trial sites in the four states.

For 32 of the 401 sites entered, and for 19 of the 197 trials entered, we have no site address information. These cases, all involving trials sponsored solely by pharmaceutical companies, have no site information on either the NCI website or the sponsoring companies' websites. Our attempts to gather information by calling these hotlines has been unsuccessful; all of the pharmaceutical companies contacted have declined our requests by phone for information about their clinical trials, citing confidentiality and proprietary information issues. Requests for this information from the companies have been met with resistance. To resolve this, we will contact the Northern California agents of the Food and Drug Administration, to discuss other approaches to obtaining this information. (See Appendix 1)

Task 2. Identify Clinical Trial Research Team Members (RTMs) (Months 1-8): We have gained approval from the UCSF Committee for Human Research (CHR) to conduct interviews with key informants (effective 21 December 2006; see Appendix 1). Using information gleaned from our online research, we have identified key personnel in several Northern California cancer centers, including Stanford Comprehensive Cancer Center, Alta Bates Comprehensive Cancer Center, and UC Davis Medical Center. We have conducted key informant interviews with two RTMs, and intend to interview another 2 RTMs within the next month.

Task 3. Develop RTM Telephone Survey Instruments (Months 5-9): After consideration of personnel hours, staff capacity and other factors, the research team decided to use multiple modes of survey data collection, including telephone surveys, self-administered paper surveys and online surveys. The existing RTM survey instrument has been reviewed and refined to meet the current study goals. Language and presentation of the instrument have been amended to reflect the multimodal approach to data collection. The key informants who have completed interviews have agreed to pretest the instrument and provide feedback. The survey will be pretested by a total of four people. We have a near final draft in progress, and anticipate having a final version of the RTM Telephone Survey within the next month. (See Appendix 2)

Task 4. Conduct RTM surveys (Months 10-16): We have gained approval from the UCSF CHR to conduct interviews with RTMs. A draft version of the RTM survey instrument is in progress. As previously indicated, we will use a multimodal approach. Two key informants have agreed to pretest the survey. After making final revisions, we will create an Access database to store RTM contact information and to track progress of the study. RTMs will be contacted by the Project Director to participate in the survey. We estimate completing interviews with 400 RTMs (one interview for each clinical site)

RTMs will have the option of completing the survey by telephone, mail or internet. Regardless of how the responses are collected, they will be entered using the web-based survey data collection software. This will establish a single dataset for all RTM survey responses, regardless of how the respondent took the survey, and ensures greater data integrity.

Task 5. Identify Community Indicators (Months 12-18): Preliminary clinical trial site data has been geocoded and plotted on maps using ArcView (see Task 1). Using these maps as a starting point, we have identified clusters of trial sites in the four states that are part of the study. We have started a review of the literature in order to identify appropriate geographic measurement units and relevant community indicators. We have also begun to identify publicly-available geographic and demographic data.

Task 6. Identify Breast Cancer Physicians in California, Florida, Illinois and New York (Months 3-8): We have investigated licensing options for the AMA Physicians MasterFile, and are in the process of negotiating terms of use. We will use this database to identify all physicians practicing surgery, oncology, or radiation oncology in the four states. Based on the data available, we will set an internal physician database for tracking and cataloguing physician contact information using MS Access. Once our internal database is established, physician data from the MasterFile will be downloaded. Completion of this task will be nearly concurrent with RTM survey (Task 4).

Task 7. Develop and Refine Survey Instrument for Physician Survey (Months 4-10): Using existing surveys, we have developed the physician survey instrument. Drafts have been reviewed and discussed among members of the research team. A final version of the instrument that has been refined to address the goals of the study is anticipated by Month 12. We have contacted several vendors of web-administered survey applications to investigate the possibility of using the software for survey data collection. We have scheduled demonstrations with three vendors, and anticipate selecting a vendor within 30 days. For the paper version of the survey, we have engaged the services of a graphic designer, who will take the lead on the visual presentation of both the hard-copy and digital versions.

We will pretest the physician survey in both paper and online forms via cognitive interviews with five physicians. Specifically, we will test for clarity and understanding and make appropriate revisions. Following cognitive testing, the survey will be tested again another 5 physicians. Both versions of the survey will then be finalized. The paper version of the survey will sent to the graphic designer; the online version will be programmed and uploaded to the server. (See Appendix 3)

Task 8. Physician Recruitment and Data Collection (Months 7-18): Upon final revisions to the physician surveys, we will initiate data collection. Paper versions of the physician surveys will be mailed to 2400 physicians (approximately 200 from each specialty, in each state) to obtain our recruitment goal of 1560 completed surveys or a 65% response rate (Months 11-16). Along with the paper version of the survey, physicians will receive an introduction letter with links to the online version of the survey, a survey username and a survey password. Physician will also be given the option of taking the survey by phone. Regardless of the data collection mode, responses will be entered using the web-based survey application. This methodology will better ensure data integrity by establishing a single dataset for all physician's responses.

Physician recruitment and data collection will take place almost concurrently with identification of breast care physicians in the four states (Task 6). Close timing will better ensure that we acquire and use the most recent information from the AMA Masterfile to contact physicians.

Key Research Accomplishments

- Identified all breast cancer clinical trials taking place in California, Florida, Illinois and New York.
- Created databases to store clinical trial characteristics and site addresses.
- Created preliminary maps of clinical trial sites in the four states
- Identified key personnel at Northern California cancer centers.
- Conducted key informant interviews
- Drafted RTM and Physician survey instruments

Reportable Outcomes

Not applicable

Conclusion

Year 01 of this study has been dedicated to laying the foundation and building the infrastructure for this study. We have completed the majority of the formative work, including identification of all breast cancer clinical trials underway in California, Florida, Illinois and New York. We have created databases to store the information we have gathered thus far, as well as near final drafts of survey instruments. Pending final revisions to the survey instruments, we are poised to go forward with the next phase of data collection, and to begin the iterative process of synthesizing all the information we have gathered.

In the process of conducting this formative work, we have encountered a few challenges. The most significant challenges have been 1) the fragmented and unstandardized nature of of clinical trial information that is publicly available on the internet, and 2) the reluctance of pharmaceutical companies to disclose non-proprietary information about their clinical trials, such as trial site locations. While these challenges have caused minor delays in the advancement of our project, we have gleaned some important insights that will further inform the next phase of data collection, synthesis and analysis.

The internet has facilitated the dissemination of information about cancer risk, screening and treatment modalities. However, in gathering data about clinical trial characteristics and trial sites, we have hound that much of the information available to the public about cancer trials is often fragmented and unstandardized. Although the PDQ® is arguably the most extensive database of clinical trials available online, the quality of information about specific clinical trials is often inconsistent. For example, comprehensive information regarding eligibility and exclusion criteria and trial location may be available for some trials but not for others through this database. We have addressed this challenge by cross-referencing, whenever possible, clinical trial information from PDQ® with comparable information found on the clinical trial sites (e.g. the UCLA Jonsson Comprehensive Cancer Center website; http://www.cancer.mednet.ucla.edu/trial-viewer/). Thus, by using multiple sources of information, we have been able to develop a composite portrait of many of the clinical trials in our study. However, in taking these remedial actions, we pause to wonder how a breast cancer patient with limited English proficiency, low literacy or no internet access, would be able to gather information about clinical trials, or how primary care providers, already strapped for time, could manage to compile this information. We will consider this challenge to collecting basic information about clinical trials in analyzing other factors that may enhance or inhibit participation of minority women in breast cancer trials.

The second challenge to advancing our project has been the reluctance of pharmaceutical companies to disclose non-proprietary information about the clinical trials they sponsor. Our requests for information, such as clinical trial locations, eligibility and exclusion criteria, and contact information for RTMs, have been met with resistance from pharmaceutical trial sponsors. The most common reasons used to justify non-disclosure are confidentiality and proprietary information issues. The findings of our study could benefit clinical trial participants and sponsoring organizations alike including pharmaceutical companies. With this in mind, we will contact local agents of the Food and Drug Administration to explore alternate approaches to obtaining clinical trial information from pharmaceutical companies.

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Appendices

Appendix 1: UCSF Committee for Human Subjects Approval Letter

Appendix 2: Key Characteristics of Clinical Trials and Clinical Trial Sites

Appendix 3: Draft of RTM Survey

Appendix 4: Draft of Physician Survey

Appendices

Appendix 1 - Appendix 2: Key Characteristics of Clinical Trials and Clinical Trial Sites

Appendix 2: Appendix 3: Draft of RTM Survey

Appendix 3: Appendix 3: Draft of Physician Survey

Appendix 1: Key Characteristics of Clinical Trials and Clinical Trial Sites

Clinical trials

General Characteristics

- Study name
- Trial phase
- Trial type
- Treatment type(s)
- Sponsoring organizations
- National Cancer Institute trial ID
- Other ID
- Targeted enrollment

Eligibility and Exclusion Criteria

- Minimum age
- Maximum age
- Disease stage
- Menopause status
- Bilateral status
- Evidence of metastasis
- Ductal Carcinoma in situ
- Nodes positive status
- Hormone receptor status
- Neu-HER status
- Performance scale (Karnofsky and ECOG)
- Life Expectancy
- Cormorbities disallowed

Clinical trial sites

Site name
Site type
Address information for General Center, Cancer Center and alternate sites:

- Street number
- Street name
- Street type
- City
- State
- Zip code
- Telephone
- Fax
- Website

Appendix 2: Draft of RTM Survey

INTRODUCTION

My name is _____and I am calling from the University of California, San Francisco. I am following up on a letter we sent to you recently, which explains our research study on minority participation in clinical trials. We received your contact information from [data source], and would like to invite you to participate in a 20-minute telephone interview.

Your experiences and insights about breast cancer clinical trials will help us better understand the barriers and facilitators minority patients face when considering whether to participate in clinical trials. We hope that the data collected through these interviews will help enhance minority participation in breast cancer clinical trials.

Your answers will remain completely confidential. Your contact information and other personally identifiable information will be kept separate from your responses.

Before we begin, do you have any questions or concerns that I may address?

Section 1:

In this section, we will ask some general questions about you and your work in clinical trials. Again, all of your answers will be kept **completely confidential** and will not be linked directly to your name or contact information.

Are you..? [Interview: ASK ONLY IF YOU CANNOT INFER GENDER.]

1	Female
2	Male

How do you describe your racial or ethnic background? (Redes)

1	Asian or Asian American
2	Black or African American
3	Latino, Latin American or Hispanic
4	Native American, American Indian or Alaska Native
5	Pacific Islander or Native Hawaiian
6	White, European American or Caucasian
7	Other: _____

In what country were you born? _____ (Redes)

Do you speak a language other than English?

1	Yes , if yes please specify: _____
0	No

How would you describe the organization where you work? Is it a…

1	Comprehensive Cancer Center	77	DK
2	Community Hospital	99	REF
3	Physician private practice		
4	Other (please specify)_____		

What is your role in your organization Are you a…

1	Principal Investigator
2	Co-Investigator
3	Clinical Trial Coordinator
4	Study Coordinator
5	Research Nurse
6	Data Manager
7	Other (please specify)_____

How many years have you worked in this capacity at your organization? | | |

How many years have you worked in clinical trial environments? | | |

How many years of school have you completed? _____years

With which of the following departments do you work most closely?

0	General Surgery
1	Surgical Oncology
2	Medical Oncology
3	Other:_____

Section 2

The next questions ask about general characteristics of clinical trials at your organization.

How many trials are you currently involved | | | in?

Which treatment modalities are involved in these trials?

1	Chemotherapy
2	Radiation
3	Surgery
4	Hormonal therapy
5	Biologic therapy
6	Stem cell
7	Bone marrow
8	Other (specify)_____

In general, who sponsors these clinical trials? Is it…

1	NCI
2	Pharmaceutical/Industry
3	Cooperative Groups (e.g. ECOG, SWOG, NSABP)
4	Other (specify)_____
77	Don't know

Section 3:

In the next section, we will ask about your breast cancer clinical trial participant population. We will ask you to estimate percentages of patients who have various characteristics. Please give your best estimate.

What percentage of your breast cancer clinical trial participants are insured by…?

a	MediCare (for people age 65+)	_____%
b	MedicAid (for low-income people; MediCal in California)	_____%
c	Fee-for-service plans/Traditional insurance plans	_____%
d	Kaiser HMO	_____%
e	Other HMO or PPO (not Kaiser or MediCare)	_____%
f	Uninsured/free care/self-pay	_____%
	Total	100 %

Thinking now of race and ethnicity, what percentage of your participants are…?

a	Asian or Asian American	_____%
b	Black or African American	_____%
c	Latino, Latin American or Hispanic	_____%
d	White, European American, Caucasian (non-Latino)	_____%
	Total	100 %

Thinking now of other characteristics, what percentage of your participants…?

a	Have less than a high school education or equivalent?	_____%
b	Need a translator to receive adequate services?	_____%
c	Are 65 years and older?	_____%
d	Have limited ability to communicate in English?	_____%
	Total	100 %

Section 4:

The questions in this section focus on breast cancer clinical trial participants with limited English proficiency. Before we continue, do you have any questions?

Does anyone on your clinical trial team speak a language other than English?

YES	1
NO	0

Does your breast cancer clinical trials have current language capabilities in…?

		YES	NO
a	English	1	0
b	Spanish	1	0
c	Chinese/Cantonese	1	0
d	Vietnamese	1	0
e	Other _____	1	0

Do patients request interpreters to help them understand clinical trial protocols?

YES	1
NO	0

Do you provide interpreter services for clinical trial participants in the following languages?

		YES	NO
a	English	1	0
b	Spanish	1	0
c	Chinese/Cantonese	1	0
d	Vietnamese	1	0
e	Other _____	1	0

⟶ **If yes to at least one language:** Which services are available?

1	Bilingual staff as interpreters
2	Face-to-face professional interpreters
3	Face-to-face volunteer interpreters
4	Telephone interpreter services
5	Video interpreter services
6	Research participant's family member or friend
7	Other/specify_____

How often are interpreter services available when needed? Would you say interpreter services are…?

1	Never available
2	Rarely available
3	Sometimes available
4	Usually available
5	Always available

→ **If no to at least one language:** Do clinical trial staff and participants communicate….

Primarily in another language	1
Equally in another language and English	2

I'm going to read a short list of materials that help explain clinical trials to research participants. Please tell me whether any of these materials are available in languages other than English.

		YES	NO	WE DON'T HAVE THE FORM
a	Consent Forms	1	0	2
b	Experimental Subject's Bill of Rights	1	0	2
c	Instructions for the procedures of study	1	0	2
d	Directions to study site	1	0	2
e	Next appointment reminders	1	0	2
f	Visual aids, such as video tapes	1	0	2
g	Materials targeting patients with low literacy	1	0	2
h	Educational materials	1	0	2

If yes: What languages are these documents available?

a	English	1	0
b	Spanish	1	0
c	Chinese (Cantonese or Mandarin)	1	0
d	Vietnamese	1	0
e	Other _____	1	0

Section 5:

The following questions ask about how you recruit participants into breast cancer clinical trials.

How much time do you spend on recruitment activities …..?

		Less than 5%	5-10%	11-15%	16-20%	21-25%
a	In general?					
b	For minorities?					

Which of the following approaches have you used to recruit research participants from diverse ethnic and language groups?

		YES	NO
a.	Recruitment videotape (for use in waiting areas of hospitals or community organizations)	1	0
b.	Advertisements in local/community newspapers	1	0
c.	Advertisements on local radio stations	1	0
d.	Discussions with potential research participants and their families by phone	1	0
e.	Presentations to community, social and service groups and churches	1	0
f.	Enlisting community members to assist with recruiting	1	0
g.	Presentations to health providers to encourage referral of their patients to the study	1	0
h.	Letters to health providers inviting them to refer their patients to the clinical trial	1	0
i.	Endorsement of the research study by well known ethnic group members	1	0
j.	Use of research staff from targeted ethnic subgroup as recruiters	1	0
k.	Participation in community health fairs or cancer awareness days	1	0
l.	Others (specify) _____	1	0

Do you use any outside/third party agencies to help with recruitment efforts for this study?

1	YES
0	NO
77	DK
99	REF

From your experience with clinical trials at your institution, which of the following incentives do you provide to participants?

A	Parking	1	0
B	Child Care	1	0
C	Monetary	1	0
D	Other	1	0

Appendix 3: Draft of Physician Survey

DOD Physician survey

As a California surgeon, oncologist or radiation oncologist, you have been randomly selected from the AMA Masterfile to participate in a survey about referral into breast cancer clinical trials.

This questionnaire takes approximately 15 minutes to complete.

All your answers will be kept completely confidential.

If you have any questions, please contact
Celia Kaplan, DrPH, at (415) 502-5601 celia.kaplan@ucsf.edu

We understand your time is valuable and greatly appreciate your assistance.

Section 1. Background Information

How old are you?_____

Are you…?

❑1	Female
❑0	Male

Which one of the following best describes your racial or ethnic background?
Check one

❑3	Asian American / Pacific Islander
❑2	Black or African American
❑1	Hispanic or Latino
❑4	Native American / American Indian
❑0	White or Caucasian
❑5	Other:_____

Where were you born?

❑0	United States
❑1	Other country: _____

Which one of the following best describes your primary practice setting?

❑0	Solo practice
❑1	Single-specialty group practice
❑2	Multi-specialty group practice
❑3	Staff-model HMO (e.g. Kaiser Permanente)
❑4	Public/community health center
❑5	Public hospital
❑6	VA hospital/clinic
	University/Medical school-based practice (not including public or VA hospitals
❑8	Other:_____

What is your medical specialty?
Check one

❑0	Oncology
❑1	Radiation Oncology
❑2	Surgery
❑3	Other: _____

Are you Board-certified in your specialty?

❑1	Yes
❑0	No

Do you have sub-specialty training?

❑1	Yes, in: _____			
	IF YES, Are you Board-certified?	**YES**	**NO**	
		❑1	❑0	
❑0	No			

Where did you graduate from medical school?

❑0	United States
❑1	Canada
❑2	Other country: _____

How long have you been in practice?: _____

Section 2. These questions help us to confirm that you are a clinician caring for breast cancer patients.

On average, what percentage of your work-related time each week do you spend in

a	Patient Care (e.g. seeing patients, calling consultants, reviewing lab results	--------- %	*If time spent in seeing patients is 10**% or less** please **stop here** and return the survey. Thank you.*
b	Teaching activities	--------- %	
c	Research activities	--------- %	
d	Administrative (committee, and other professionally-related activities)	--------- %	
	TOTAL	**100**%	

On average, what percentage of patients in your practice are women with breast cancer including ductal carcinoma in situ (DCIS)?

Percent women: _____%

*If **10% or less of your patients are women with breast cancer or DCIS***
*Please **stop here** and return the survey. Thank you.*

How many active breast cancer patients (newly diagnosed or undergoing treatment) have you seen in your office within the past 12 months?

Number of cases: _____

Section 3. The following questions relate to the patients in your practice.

What percentage of your breast cancer patients would you estimate has?

a	Medicare	_____%
b	Medical	_____%
c	Private or Fee for service	_____%
d	Kaiser Insurance	_____%
e	Managed Care (non-Kaiser, non-Medicare)	_____%
f	Uninsured/ free care/ self-pay	_____%
	Total	**100%**

a	Less than the equivalent of a high school education?	_____%
b	Need a translator to receive adequate services?	_____%
c	Are 65 years and older?	_____%
d	Has limited ability to communicate in English?	_____%

In your practice, what percentage of your breast cancer patients are:

a	Asian or Asian American	_____%
b	Black or African American	_____%
c	Latino, Latin American or Hispanic	_____%
d	White, European American, Caucasian	_____%
	Total	**100%**

Please think now about your office and clinical staff. Are any of the following staff members Bilingual?

		Yes	No
a	Receptionist/front desk	1	0
b	Appointment desk/phone	1	0
c	Office manager	1	0
d	Nursing assistant/CNA	1	0
e	Nurse	1	0
f	Physicians assistant/ Nurse Practitioner	1	0
g	Physician	1	0

In what languages does your office have written information on cancer information available to patients?

		Yes	No
a	English	1	0
b	Spanish	1	0
c	Chinese	1	0
d	Vietnamese	1	0
e	Our office does not have cancer written information	1	0

Section 4. The following questions are related to your involvement in research and your relationship with research institutions

Please tell us about your interaction with university medical centers

		Yes	No
a	Do you have a faculty appointment at a medical school?	1	2
b	Do you have admitting privileges at a university medical center or major teaching affiliate?	1	2
c	In the last two years, have you consulted with a physician at a university medical center about clinical trials or a patient's eligibility for a clinical trial?…….	1	2

In your practice, what has been your involvement in clinical trials?.

		Yes	No
a)	I have had patients inquire about clinical trials……	1	2
b)	I have referred patients to clinical trials administered by others…….	1	2
c)	I have administered a clinical trial as a Principal Investigator or Co-Investigator	1	2
d)	I have recruited patients for a clinical trial for which I am a Principal Investigator or Co-Investigator.	1	2
e)	I have participated in the evaluation of a clinical trial	1	2
f)	I have participated in a clinical trial in other ways	1	2
g)	I have never had any involvement in a clinical trial.	1	2

Are you currently a Principal Investigator or Co-Investigator of a cancer trial?

Yes…….1	a) If yes, what kind of trial?_____
No……..2	

In the past five years, how many trials have you been involved in as an investigator?

_____

In regard to breast cancer clinical trials and patients in your practice, how often do you…?
Circle one

		Very Often	Often	Sometimes	Rarely	Never
a	Discuss the possibility of enrolling your patients in clinical trials	1	2	3	4	5
b	Discuss a specific clinical trial	1	2	3	4	5
c	Give written information about a clinical trial to your patients	1	2	3	4	5
d	Refer patients to sources (e.g. internet, ACS) where they might learn more about clinical trials in general.	1	2	3	4	5
e	Weigh the potential benefits and risks/burden of a specific clinical trial(s) with your patients	1	2	3	4	5
f	Obtain permission to have a staff person from a clinical trial call the patient to give them more information.	1	2	3	4	5
g	Encourage patients to participate in a clinical trial(s)	1	2	3	4	5
h	Refer patients to government-funded (NCI) trials	1	2	3	4	5
i	Enroll patients in industry-funded trials	1	2	3	4	5
j	Enroll patients in government-funded (NCI) trials	1	2	3	4	5

Who typically initiates a discussion about clinical trials

My Patients initiate	1
I initiate…...	2
My patients and I initiate equally	3
I do not discuss trials with patients……	4

If you refer patients to clinical trials, how often do you refer them to …?

	Drug	Very Often	Often	Sometimes	Rarely	Never
a	Surgical trial	1	2	3	4	5
b	Radiation trial	1	2	3	4	5
c	Biological Agent trial	1	2	3	4	5
d	Adjuvant/Neoadjuvant therapy	1	2	3	4	5
e	None	1	2	3	4	5

COMMITTEE ON HUMAN RESEARCH
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CHR APPROVAL LETTER

TO: Celia Patricia Kaplan, Dr.P.H., M.A.
Box 0856

RE: Inclusion of Minority Patients in Breast Cancer Clinical Trials: The Role of the Clinical Trial Enviornment

The Committee on Human Research (CHR) has reviewed and approved this application to involve humans as research subjects. This included a review of all documents attached to the original copy of this letter.

Specifically, the review included but was not limited to the following documents:
Key Informant and Physician Consent Forms, Dated 11/30/06

The CHR is the Institutional Review Board (IRB) for UCSF and its affiliates. UCSF holds Office of Human Research Protections Federalwide Assurance number FWA00000068. See the CHR website for a list of other applicable FWA's.

APPROVAL NUMBER: H9066-27862-02. This number is a UCSF CHR number and should be used on all correspondence, consent forms and patient charts as appropriate.

APPROVAL DATE: December 21, 2006 **EXPIRATION DATE:** December 21, 2007 **Expedited Review**

GENERAL CONDITIONS OF APPROVAL: Please refer to www.research.ucsf.edu/chr/Apply/chrApprovalCond.asp for a description of the general conditions of CHR approval. In particular, the study must be renewed by the expiration date if work is to continue. Also, prior CHR approval is required before implementing any changes in the consent documents or any changes in the protocol unless those changes are required urgently for the safety of the subjects.

HIPAA "Privacy Rule" (45CFR164): This study does not involve access to, or creation or disclosure of Protected Health Information (PHI).

Sincerely,

Alan P Venook

Alan P. Venook, MD
Chair, Committee on Human Research

cc:

Grant Number: BC050899
Contract Number: W81XWH-06-1-0254